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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,928	10/31/2003	Serge Boyer	45198.00046.UTL	2990

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EXAMINER

SOLOLA, TAOFIQ A

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/698,928

Applicant(s)

BOYER ET AL.

Examiner

Taofiq A. Solola

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Claims 1-19 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-9, 16-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification lacks support for claims 3-9 and 16-19 as claimed. According to the specification, applicant developed a method of improving the delivery of therapeutic agents by developing phosphonate adducts of the agents. The adduct dissociates at the site of action, releasing the agent wherein applicant's invention ends. The agent alone is responsible for therapeutic activity at the point of action, and there is no evidence in the specification that applicant developed the active agent or discovered its utility. By deleting the claims the rejection would be overcome.

The specification lacks adequate support for claims 3 and 16-19. The claims are drawn to any diseases of P450 expressing tissues. The claims must recite only the specific diseases having support in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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Claims 2-3, 8, 13-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For reasons set forth above under 35 USC 112, first paragraph, claims 3, 16-19 are indefinite.

Claim 2 improperly depends from claim 1 for failure to limit the scope of claim 1. Claim 14 fails to limit the scope of claim 13. Independent claims 1 and 13 are drawn to species described in formula I, while dependent claims 2 and 14 are drawn to the same species represented by its chemical structure. Claim 8 fails to limit the scope of claim 7. The phraseology "preventing the recurrence of cancers" implies the animal is cancer free in claim 7. By deleting claim 8 and any set of claims 1-2, 13-14 the rejection would be overcome.

The phraseology "a pharmaceutically effective amount of oncolytic agent," lines 10-11, claim 13, is idiomatic and therefore renders claims 13-15 indefinite. By inserting "an" between "of" and "oncolytic" the rejection would be overcome.

Claim 15 is improperly depend from claim 13. Claim 13 is drawn to a composition while claim 15 refers to claim 13 as method of use.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erion et al., WO 99/45016.

Applicant claims a compound represented by formulae I and III, composition and method of use for increasing therapeutic index, treating disease of P450 tissues (primarily liver) and cancers. Applicant also claims the composition further comprising an oncolytic agent (cocktail). In the formulae, M is cytarabine (a nucleoside), and V is 4-pyridyl.

Determination of the scope and content of the prior art (MPEP 2141.01)

Erion et al, teach a similar compound, composition and method of use for increasing therapeutic index, treating diseases of the liver, metabolic diseases and cancers. M is any nucleoside, bioactive agent or drug and V is 4-pyridyl. See the entire document particularly, pages 7-15, 54-55, 62-63, the examples and claims.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant invention and that of Erion et al., is that applicant is claiming composition further comprising an oncolytic agent (cocktail) and M as cytarabine instead of any nucleoside, bioactive agent or drug by Erion et al.

Finding of prima facie obviousness---rational and motivation (MPEP 2142.2413)

The combination of compounds for a certain function where the compounds are known to have the function individually is prima facie obvious. *In re Kerkhoven*, 205 USPQ 1069 (1980). It is also obvious from routine practice of medicine of treating patients with combination therapies by using cocktail medications, administered separately or together. Therefore, the instant invention is prima facie obvious from the teaching of Erion et al. One of ordinary skill in the art would have known to use cytarabine, a known nucleoside, bioactive agent or drug, and claim a cocktail at the time the invention was made. The motivation for claiming cytarabine (a

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nucleoside) is from the teaching of Erion et al., that M is any nucleoside, bioactive agent or drug, and the cocktail composition is from routine practice of medicine.

Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34, 53-60, 95-145, 147-172 of U.S. Patent No. 6,312,662. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims are drawn to the same subject matter and the instantly claimed invention is in the claims of US '662. In some of the compounds of US '662, Z, W, W' are not H at the same time, some of them must be alkyl, while in the instant application V, Z, W, W' are all H. However, H and alkyl are art recognized equivalents. *In re Lincoln*, 126 USPQ 477, 53 USPQ 40 (CCPA, 1942); *In re Druey*, 319 F.2d 237, 138 USPQ 39 (CCPA, 1963); *In re Lohr*, 317 F.2d 388, 137 USPQ 548 (CCPA, 1963); *In re Hoehsema*, 399 F.2d 269, 158 USPQ 598 (CCPA, 1968); *In re Wood*, 582 F.2d 638, 199 USPQ 137 (CCPA, 1978); *In re Hoke*, 560 F.2d 436, 195 USPQ 148 (CCPA, 1977); *Ex parte Fauque*, 121 USPQ 425 (POBA, 1954); *Ex parte Henkel*, 130 USPQ 474, (POBA, 1960).

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Specification

The specification is object to for having numerous abbreviations, which are not common chemical nomenclature and are not defined in the specification on first occurrence in accordance with standard scientific practice.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD., JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.


TAOFIQ SOLOLA
PRIMARY EXAMINER
Group 1626

June 17, 2005